

Appl. No. : 10/659,698
Filed : September 11, 2003

REMARKS

A. Disposition of Claims

Claims 15-17, 19, and 23-25 are pending in this application. Claims 1-13, 20, and 21 have been canceled without prejudice as being drawn to non-elected subject matter. Claims 14, 18, and 22 have been canceled without prejudice preliminary to further prosecution on the merits. Claims 15-17, 19, and 23-25 have been amended to conform to the PEGylated embodiment, and thus for reasons unrelated to patentability. The title has been edited to be more descriptive. The first paragraph of the specification has been amended to indicate a related application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

B. Compliance with 35 USC 112/1

The Patent Office rejected Claims 14-16, 18 [sic, and 22] under 35 USC 112/1 as failing to meet the enablement requirement. The Examiner agrees that the PEGylation embodiment is enabled. Office Action at p. 4, line 17. Claims 15-17, 19, and 23-25 have been amended to conform to the PEGylated embodiment. The conclusion is the claims are in compliance with 35 USC 112/1 as meeting the enablement requirement.

C. Compliance with 35 USC 103(a)

The issue is whether the claims are in compliance with 35 U.S.C. §103(a) or unpatentable as being obvious over **Smith et al., Journal of General Microbiology 128: 307 (1982) in view of Nucci et al., Advanced Drug Delivery Reviews 6: 133 (1991), full article attached.** The rule according to MPEP 2143 is that to establish a *prima facie* case of obviousness: First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Here, such suggestion or motivation is missing, thus negating a *prima facie* case of obviousness. Smith et al. describes a problem associated with use of bacteriophage as antibiotics in that phage stimulate antibodies, which could clear the phage and be a complication of phage therapy. Nucci et al. describes use of PEG for modification of proteins to prolong their circulating life. In contrast, the claims are directed to bacteriophage that have been PEGylated to escape the host defense system. While Nucci et al. describes proteins, and, on page 144, 3rd full paragraph, futuristically, other compounds that can benefit from being PEGylated, such as

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chemical drugs and other chemical compounds, tissues and organs that “theoretically” can have PEG attached, and PEGylation to develop functionalized vaccines, nowhere does Nucci et al. extend the discussion of proteins that can benefit from being PEGylated to bacteriophage. There was nothing in the prior art to teach the equivalence, and thus the obviousness, of making the substitution of bacteriophage for proteins. To the contrary, the very art of Nucci et al. indicated that PEGylation of live entities, such as tissues and organs, was merely “theoretical” and did not mention single cells. In contrast, bacteriophage are “live” viruses that infect bacteria and are more analogous to single cells, which were left off the list of even “theoretical” candidates for PEGylation. Additionally, Nucci et al. established that proteins were the only compounds presently being PEGylated and that, futuristicly, other compounds could benefit from PEGylation, but this was pure speculation. Finally, Nucci et al. revealed that vaccines could be PEGylated, but the purpose of vaccines is to *retain* immunogenicity, while the purpose of PEGylating bacteriophage would be to *reduce* immunogenicity to escape the HDS, thus actually teaching away from bacteriophage. In sum, Nucci et al. did not explicitly mention bacteriophage, any implicit mention of other PEGylation possibilities is futuristic and speculative, and Nucci et al. actually teaches away from bacteriophage. The substitution was an ingenious solution to the prior art problem that was solved by none other than the inventors. There was no reason to combine these references to arrive at the claimed invention because bacteriophage were not considered by those of ordinary skill in the art equivalent to proteins. As there was no suggestion or motivation to modify the reference or combine reference teachings, a *prima facie* case of obviousness cannot stand. The conclusion is that the claims are non-obvious over the references. Thus, the claims are in compliance with 35 U.S.C. §103(a).

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CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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AMEND

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